UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **December 27, 2021**

TRACON Pharmaceuticals, Inc.		
(Exact name of registrant as specified in its charter)		
Delaware	**001-36818**	**34-2037594**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

4350 La Jolla Village Drive, Suite 800 San Diego, California	**92122**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (858) 550-0780

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Securities Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	TCON	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On December 27, 2021, the Company issued a press release announcing the Independent Data Monitoring Committee's (IDMC) recommendation following the interim analysis from the pivotal ENVASARC Phase 2 clinical trial of envafolimab (cohort A) and envafolimab in combination with Yervoy (cohort B) in the soft tissue sarcoma subtypes of Undifferentiated Pleomorphic Sarcoma (UPS) and Myxofibrosarcoma (MFS).

The IDMC reviewed interim safety and efficacy data from 18 patients enrolled into each cohort who completed a minimum of 12 weeks of efficacy evaluations (two on-treatment scans). The objective response rate (ORR) by blinded independent central review (BICR) in each cohort satisfied the prespecified futility rule. Envafolimab was well tolerated, with only a single Grade 3 related adverse event reported in 36 patients. Based on the tolerability profile and the significantly higher ORR observed in lower weight patients, the IDMC recommended the trial continue using a higher dose of envafolimab of 600 mg every three weeks, which is twice the current envafolimab dose of 300 mg every three weeks.

Given the robust activity demonstrated by higher doses of envafolimab in completed studies, including in the pivotal trial in MSI-H/dMMR cancer that was the basis for approval in China, TRACON agrees with the IDMC guidance and expects to propose a doubling of the envafolimab dose to 600 mg every three weeks to the FDA in a protocol amendment, but to otherwise continue the existing trial schema and assess up to 80 new patients in cohort A of single agent envafolimab and up to 80 new patients in cohort B of envafolimab with Yervoy, with nine of 80 responses by BICR in either cohort needed to satisfy the primary objective of the study to statistically exceed the known 4% ORR of Votrient (pazopanib), the only approved treatment for patients with refractory UPS or MFS. The Company expects the delivery of the final endpoint of ORR in 2023.

The press release issued on December 27, 2021 is attached hereto as Exhibit 99.1.

Forward-Looking Statements

Statements made in this report regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding TRACON's plans to further develop product candidates, expectations regarding the timing, cost and scope of clinical trials, plans with respect to potential protocol amendments and the impact thereof, expected development and regulatory milestones and timing thereof, and the potential benefits of product candidates. Risks that could cause actual results to differ from those expressed in these forward-looking statements include: risks associated with clinical development; whether TRACON or others will be able to complete or initiate clinical trials on TRACON's expected timelines, if at all, including due to risks associated with the COVID-19 pandemic or other pandemics; the fact that future clinical results may not be consistent with preliminary results or results from prior studies; the fact that TRACON has limited control over whether or when third party collaborators complete on-going trials, initiate additional trials or seek regulatory approval of TRACON's product candidates; the timing and outcome of meetings with regulatory agencies; the fact that TRACON's collaboration agreements are subject to early termination; whether TRACON will be able to enter into additional collaboration agreements on favorable terms or at all; potential changes in regulatory requirements in the United States and foreign countries; TRACON's reliance on third parties for the development of its product candidates, including the conduct of its clinical trials and manufacture of its product candidates; whether TRACON will be able to obtain additional financing; and other risks described in TRACON's filings with the Securities and Exchange Commission under the heading "Risk Factors". All forward-looking statements contained in this report speak only as of the date on which they were made and are based on management's assumptions and estimates as of such date. TRACON undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description

99.1	Press release issued by TRACON Pharmaceuticals, Inc. on December 27, 2021.
104	Cover page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: December 27, 2021

TRACON Pharmaceuticals, Inc.

By: /s/ Charles P. Theuer, M.D., Ph.D.
Name: Charles P. Theuer, M.D., Ph.D.
President and Chief Executive Officer

Exhibit 99.1

TRACON Pharmaceuticals Announces Positive Results from the Independent Data Monitoring Committee Review of Interim Safety and Efficacy Data from the Ongoing ENVASARC Pivotal Trial

Pre-specified Interim Analysis Concluded with Recommendation to Continue the ENVASARC Trial

Objective Response Rate (ORR) by Blinded Independent Central Review (BICR) in Each Cohort Satisfied the Bar for Futility and Supports Continued Accrual

Envafolimab Well Tolerated as a Single Agent and in Combination with Yervoy

San Diego, CA – December 27, 2021 – TRACON Pharmaceuticals (NASDAQ: TCON), a clinical stage biopharmaceutical company focused on the development and commercialization of novel targeted cancer therapeutics today announced the Independent Data Monitoring Committee (IDMC) for the ongoing ENVASARC pivotal trial recommended continued accrual as planned in both cohort A of single agent envafolimab and cohort B of envafolimab given with Yervoy (ipilimumab).

The IDMC reviewed interim safety and efficacy data from 18 patients enrolled into each cohort who completed a minimum of 12 weeks of efficacy evaluations (two on-treatment scans). The ORR by BICR in each cohort satisfied the prespecified futility rule. Envafolimab was well tolerated, with only a single Grade 3 related adverse event reported in 36 patients.

Based on the highly tolerable safety profile and the significantly higher ORR observed in lower weight patients, the IDMC recommended increasing the envafolimab dose to 600 mg Q3W, which is twice the current envafolimab dose of 300 mg Q3W. Given the robust activity demonstrated by higher doses of envafolimab in completed studies, including in the pivotal trial in MSI-H/dMMR cancer that was the basis for approval in China, TRACON agrees with the IDMC guidance and will recommend this dose to the U.S. Food and Drug Administration (FDA) through a protocol amendment.

“We are pleased that envafolimab has demonstrated clear activity as a single agent and in combination with Yervoy even at this early 12-week time point. The increase in dose is supported by the safety profile observed to date, which we believe may further differentiate envafolimab from the current standard of care. Envafolimab has been dosed safely at doses that are eight-fold higher than those currently used in ENVASARC. We therefore believe a doubling of the dose can be administered safely and result in higher envafolimab exposures, thereby potentially optimizing envafolimab’s efficacy for the greatest number of sarcoma patients,” said James Freddo, M.D., TRACON’s Chief Medical Officer. “This interim analysis is an important milestone for Tracon. We look forward to working closely with the FDA on an amendment to implement the IDMC’s recommendations. We are excited by the emerging data and for envafolimab’s potential to become a differentiated treatment for sarcoma patients.”

About Envafolimab

Envafolimab (KN035), a single-domain antibody against PD-L1 invented by Alphamab Oncology, is the first subcutaneously injected PD-(L)1 inhibitor approved by the NMPA in November 2021 in adult patients with MSI-H/dMMR advanced solid tumors who failed systemic treatment and have no satisfactory alternative treatment options. In December 2019, Alphamab Oncology, 3D Medicines and TRACON entered into a collaboration whereby TRACON has the right to develop and commercialize envafolimab in soft tissue sarcoma in North America. Envafolimab is currently being studied in the pivotal ENVASARC Phase 2 trial in the U.S. sponsored by TRACON and a Phase 3 pivotal trial in combination with gemcitabine and oxaliplatin in advanced biliary tract cancer patients in China sponsored by TRACON's corporate partners, Alphamab Oncology and 3D Medicines.

About ENVASARC (NCT04480502)

The ENVASARC pivotal trial is a multicenter, open label, randomized, non-comparative, parallel cohort study at approximately 25 top cancer centers in the United States that began dosing in December 2020. TRACON expects the trial to enroll 160 patients with UPS or MFS who have progressed following one or two lines of prior treatment and have not received an immune checkpoint inhibitor, with 80 patients enrolled into cohort A of treatment with single agent envafolimab and 80 patients enrolled into cohort B of treatment with envafolimab and Yervoy. The primary endpoint is ORR by BICR with duration of response a key secondary endpoint.

About TRACON

TRACON develops targeted therapies for cancer utilizing a capital efficient, CRO independent, product development platform. The Company's clinical-stage pipeline includes: Envafolimab, a PD-L1 single-domain antibody given by rapid subcutaneous injection that is being studied in the pivotal ENVASARC trial for sarcoma; YH001, a potential best-in-class CTLA-4 antibody in Phase 1 development; TRC102, a Phase 2 small molecule drug candidate for the treatment of lung cancer; and TJ004309, a CD73 antibody in Phase 1 development for the treatment of advanced solid tumors. TRACON is actively seeking additional corporate partnerships whereby it leads U.S. regulatory and clinical development and shares in the cost and risk of clinical development and leads U.S. commercialization. In these partnerships TRACON believes it can serve as a solution for companies without clinical and commercial capabilities in the U.S. To learn more about TRACON and its product pipeline, visit TRACON's website at www.traconpharma.com.

Forward-Looking Statements

Statements made in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding TRACON's plans to further develop product candidates, expectations regarding the timing and scope of clinical trials, plans with respect to potential protocol amendments and the impact thereof, expected development and regulatory milestones and timing thereof, the potential benefits of product candidates, and TRACON's business development strategy and goals to enter into additional collaborations. Risks that could cause actual results to

differ from those expressed in these forward-looking statements include: risks associated with clinical development; whether TRACON or others will be able to complete or initiate clinical trials on TRACON's expected timelines, if at all, including due to risks associated with the COVID-19 pandemic or other pandemics; the fact that future clinical results may not be consistent with preliminary results or results from prior studies; the fact that TRACON has limited control over whether or when third party collaborators complete on-going trials, initiate additional trials or seek regulatory approval of TRACON's product candidates; the timing and outcome of meetings with regulatory agencies; the fact that TRACON's collaboration agreements are subject to early termination; whether TRACON will be able to enter into additional collaboration agreements on favorable terms or at all; potential changes in regulatory requirements in the United States and foreign countries; TRACON's reliance on third parties for the development of its product candidates, including the conduct of its clinical trials and manufacture of its product candidates; whether TRACON will be able to obtain additional financing; and other risks described in TRACON's filings with the Securities and Exchange Commission under the heading "Risk Factors". All forward-looking statements contained in this press release speak only as of the date on which they were made and are based on management's assumptions and estimates as of such date. TRACON undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Company Contact:
Mark Wiggins
Chief Business Officer
(858) 251-3492
mwiggins@traconpharma.com

Investor Contact:
Brian Ritchie
LifeSci Advisors LLC
(212) 915-2578
britchie@lifesciadvisors.com